

Description

Field of the invention

[0001] This invention relates to a method and apparatus for non-invasive measurement of blood pressure, and, in particular, relates to a so-called oscillometric method and the corresponding apparatus for intermittent measurement of arterial blood pressure, as well as a so-called vascular unloading method and the corresponding apparatus for continuous measurement of arterial blood pressure.

Background of the invention

[0002] Oscillometric method is based on the principle that the blood vessel will be the most flexible (This state is called the "unloading state.") and will be flattened separately when the external pressure of the artery is equal to the mean blood pressure and higher than the internal systolic blood pressure. Since the internal blood pressure of the artery is changing periodically along with the heart beat at all time (during a heartbeat cycle, the highest pressure is called systolic blood pressure, the lowest pressure is called diastolic blood pressure, and the average of the all pressure value over the heartbeat cycle is called the mean blood pressure), and the diameter (or volume) is changing periodically with the blood pressure so as to form the arterial pulse. The amplitude of the pulse will be maximum when the external pressure of the vessel is equal to the mean blood pressure so that the vascular wall is the most flexible, and the amplitude of the pulse will disappear when the external pressure of the vessel is higher than the systolic blood pressure so that the blood vessel is flattened. When measuring the blood pressure by using oscillometric method, at first, an air bladder (or liquid bladder) to apply the external pressure to the artery is fixed on the skin over the artery. Then the pressure of the bladder is changed, linearly or step by step, within the range that the lower limit is lower than the mean blood pressure and upper limit is higher than the systolic blood pressure at a rate of about 3 mmHg/sec. At the same time, the change in pulse amplitude is measured by a pulse transducer during the entire course. If the bladder pressure can be transmitted accurately to the outside of the blood vessel through the soft tissues under the center of the bladder and the pulse transducer can detect the arterial pulse from these soft tissues, the pressure will be equal to the mean blood pressure and the systolic blood pressure separately when the pulse amplitudes are at their maximum and close to disappearance. Therefore, the mean blood pressure and the systolic blood pressure can be measured by measuring the bladder pressure at the two moments using a pressure transducer. Furthermore, making use of the measured mean blood pressure and systolic blood pressure, the diastolic blood pressure can be calculated according to the experiential formula, i.e.

diastolic blood pressure = (3 X mean blood pressure - systolic blood pressure)/ 2 obtained. This method can only measure blood pressure intermittently because each process of pressure change for one cycle of measurement of the blood pressure needs a considerable amount of time. However, comparing with traditional Auscultatory method (or Korotkoff sound method), Palpatory method, flush method, as well as Doppler ultrasound kinetoarteriography method, the oscillometric method is able to measure the mean blood pressure and to avoid the errors caused by artificial differences. It is also simple in device structure and easy to use. In addition, comparing with pressure oscillometric method which has been applied widely to clinics and families, the method can measure accurately instead of statistic calculating the systolic blood pressure.

[0003] Vascular unloading method is based on the principle that the diameter of the blood vessel will not change with the wave of the blood pressure in the vessel (or will not pulsate), but will maintain at its unloading state when the pressure outside the vessel is equal to the internal blood pressure at any given time. This method includes an air bladder (or liquid bladder) that applies the external pressure to the artery and a pulse transducer, and a feedback control system which uses the measured artery pulse to control the pressure of the air bladder. When measuring the blood pressure continuously by using vascular unloading method, at first, like the oscillometric method, the air bladder pressure is changed in a certain range, and at the same time, the change in pulse amplitude in the bladder pressure is measured. When the bladder pressure is equal to the mean pressure in the artery so that the vascular wall is the most flexible, and the amplitude of the pulse is the highest, the feedback control system is connected to magnify the measured signal of the pulse and phase compensate. The feedback control system is further used to control the bladder pressure so that it will change according to the pulse wave on the base of the mean pressure. Once the wave of the pressure on the outside of the blood vessel is made the same as the wave of the periodical change of the blood pressure inside the artery, both in shape and amplitude, so that the force on both the inside and outside the vessel wall reaches a dynamic balance, the diameter of the artery vessel, instead of changing with the wave of the intravascular blood pressure, will be maintained at its unloading state; i.e. the pulse oscillation amplitude is near zero. At this time, if the bladder pressure is continuously measured by a pressure transducer, the continuous measurement of the instantaneous blood pressure (i.e. blood pressure wave) can be obtained. Because it is non-invasive, comparing with the traditional invasive continuous blood pressure measurement method by introducing a catheter connected a pressure transducer into the artery to be measured, the vascular unloading method will not cause the complications and sequelae such as bleeding, infection, formation of thrombus, embolism, nerve damage and so on.

In addition, its operation is greatly simple. Also, comparing with the tonometric technique (also called "reactive force method"), which appeared in recent years, the vascular unloading method also possess many advantages, for example, it does not need calibration, and the measured result is not easily affected by the patient's body movement.

[0004] The two methods mentioned above are not currently used on the upper arm where the blood pressure is normally measured, but on the finger to measure the blood pressure of the finger artery. This is mainly because that the position of the brachial artery of the upper arm is very deep, so that the external pressure must be applied to the upper arm from all-rounded or near all-rounded of the arm, so as to transmit adequately the external pressure to the brachial artery. Because of the pressure, long-term frequent use of the oscillometric method to measure the blood pressure intermittently or keeping using the oscillometric method to measure the blood pressure continuously will all seriously affect the blood circulation and nerval function of the entire lower arm and the hand. However, the position of the finger artery is shallow, when measuring the finger blood pressure, the influence on the blood circulation and nerval function of the finger, caused by the increased bladder pressure, is smaller.

[0005] Numerous clinical experience results have shown that the two methods have another big problem when the finger is used for measuring blood pressure, that is, because the finger artery belongs to distal arteriolar, comparing with the so-called "system blood pressure" (or the blood pressure of the aorta near the heart) that is used clinically when judging whether the patient's blood pressure is normal or not, blood pressure of finger is around 10 mmHg lower under normal conditions. In case of arteriosclerosis, the difference can reach several ten mmHg. More importantly, because the composition of the smooth muscle inside the small artery vessel wall is larger than that in the aortal wall, and these vascular smooth muscle are very easily affected by various factors (such as coldness, anaesthesia, etc.) so as to either produce vasoconstriction or vasodilation, which causes the blood pressure in the small artery to wave at a great range, under many circumstances, the blood pressure obtained from finger artery cannot be used to reflect the system blood pressure of the patient. Especially when the patient's circulation function is very weak, the finger artery can sometimes cause the loss of blood in the artery due to the extreme vasoconstriction of the vascular smooth muscle, so the blood pressure cannot be measured on the finger.

[0006] In order to correctly reflect the system blood pressure while not affecting the blood circulation of the distal part of the measured area, a proposal to change the measuring position of the two methods to the wrist has recently been made, and also changing the traditional all-rounded pressure bladder to a local pressure bladder so as to only give pressure to one of the two

arteries in the wrist (radial artery and ulnar artery) has been considered. This is based on two points: first, the diameter of the radial artery or ulnar artery is much bigger than the finger artery, and the composition of the smooth muscle in the vessel wall is less than in the finger artery, so their blood pressure is closer to the system blood pressure than that of the finger artery and temporal artery, and also not easily affected by other factors. In addition, even when the patient's circulation function is very weak, the pulse can be always detected from the radial artery or ulnar artery, making the measurement of the blood pressure possible. Because of the above mentioned advantages of the wrist arteries and the fact that it is easy to operate on the wrist, invasive direct measurement of radial artery blood pressure on the wrist has been the most frequently used method of the blood pressure measurement for many years in applying to surgery and monitoring the critically ill, so that the radial blood pressure has been habitually used as the most reliable and accurate judgement of the system blood pressure. Therefore, changing the measuring position of the two methods to the wrist has an extreme value of clinical application.

[0007] Secondly, normal people have more than two bigger arteries and veins on the wrist, of which, two arteries (radial artery and ulnar artery) are connected to each other by two arterial arches in the palm; several veins on the back of the hand are also connected to each other by the vain web on the back of the hand. The connection of the these blood vessels guarantees that, even if one artery and/or part of the vein is occluded (has an occlusion) for a long time, but the other artery and the rest parts of the veins will still have a smooth blood flow, the circulation of the hand will basically not be affected. Therefore, frequent and continuous blood pressure measurement can be performed for a long time with these two methods on one wrist artery of either the radial artery or ulnar artery.

[0008] Although related researches have shown that the mean blood pressure, systolic blood pressure, or the blood pressure wave can be separately and accurately measured, with oscillometric method and vascular unloading method, on the radial artery near the most protuberant spot on the volar aspect of the distal end of the radius, research has also discovered that it is actually very difficult to measure the blood pressure accurately on the wrist. It is mainly because the precision of the blood pressure measurement is very sensitive to the measuring position so even on the most protuberant spot on the volar aspect of the distal end of the radius, on various positions with a difference of only 2,3mm among them, the measured blood pressure can be greatly different. In addition, the precision of the measurement can also be affected by outside factors. First, the measured blood pressure will vary greatly when the wrist turns with the long axis of the forearm as the axis of rotation, or when the hand bends towards the palm side or the back side of the hand. Secondly, along with

the increased bladder pressure, the bladder might move towards not only the center of volar aspect of wrist along the circumferential direction, but also the hand along the long axis of wrist. All these movements may change the bladder volume, and the movement in the direction of circumference and long axis may also cause the pulse transducer to move its position. Among these, the position change of the pulse transducer may affect the measuring precision of the oscillometric method and the vascular unloading method, and the change of the bladder volume will especially affect the precision of the vascular unloading method. It may even affect the stability of its feedback control system. On the other hand, these studies have also discovered that because the holding strap of the bladder may put great pressure to the wrist and other parts, after long time, continuous measuring, the blood circulation and nerval function of the hand which is bellow the air bladder may also be greatly affected. Especially long, continuous pressure from the air bladder will cause pain in the part that is under the bladder pressure.

Summary of the invention

[0009] The goal of the invention is to provide a method and a device which can make use of the principles of the oscillometric method and the vascular unloading method to, simply and accurately, measure the intermittent or continuous blood pressure of the radial and/or the ulnar artery without obvious influence of the above mentioned factors, and also effectively eliminate the influence on the blood circulation and nerval function of the hand due to long-term, continuous measurement.

[0010] To reach the above-mentioned goal, the solution has been invented as follows:

1. At least, the angle between the wrist and the hand is kept to the most suitable degree for measuring the blood pressure of the radial artery. In addition, it is preferred to keep the turning angle of the wrist relative to the middle part of the forearm to the most suitable degree for measuring the radial arterial blood pressure. The cooperative position of the two angles can lower the position of the tendon and the nerves nearby the radial artery and make the radial artery to a position nearest to the radius bellow it, so that the bladder can effectively press the radial artery. When measuring the blood pressure repeatedly or continuously for a long-term, in order to guarantee the above-mentioned location for the measurement on the wrist, this invention also uses a wrist holding bracket to hold the wrist bending position of the and the hand turning angle so that when the patient moves, the position of the pressure bladder and the pulse transducer, as well as the tendon, nerves, and radius in the wrist relative to the radial artery, stays the same during the measurement.

2. In order to find the precise position easily to most

accurately measure the blood pressure of the radial artery, a pulse transducer array is fixed on the center of the pressure area of the pressure bladder placed on the skin over the most protuberant spot on the volar aspect of the distal end of the radius. When changing the bladder pressure, the pulse signals of the radial artery are measured from many different positions on the wrist by the pulse transducer array through the entire bladder pressure changing process. These signals are feed to a optimal site selector. The amplitude of the pulse signal measured by the transducer near the radial artery is large, and the mean and systolic blood pressure corresponding the pulse signal measured on the site with the optimal pressure transmission are lower. In order to find the site most suitable for measuring the radial arterial blood pressure based on the above facts, first, the optimal site selector choose a column of the pulse signals with the largest amplitude during the maximum oscillation among all the columns of the pulse signals detected from the transducers arranged parallel to the radial artery; Secondly, the optimal site selector choose a channel of the pulse signal from the selected columns of the pulse signals. The selected signal should possess not only maximum oscillation through the entire changing process of the bladder pressure, but also being closed to oscillation disappearance during the bladder pressure is higher than the pressure corresponding to the maximum oscillation amplitude; Furthermore, the bladder pressures corresponding to the maximum and the disappearance of pulse amplitude of the selected signal is the lowest. The selected signal is used as the optimal site signal to measure the blood pressure of the radial artery with the oscillometric or compensation method. Meanwhile, for placing the bladder center, where the pressure transmission is the deepest, to correspond to the site selected for the most accurate measurement of the radial arterial blood pressure, the site of the transducer obtained optimal pulse signal in the array is displayed in the most visual way. Thus, the position of the pressure bladder is adjusted so that the transducer detected the optimal pulse signal is at the center of the transducer array. In addition, when measuring the blood pressure for a long-term, automatic periodical check should be done to make sure if the transducer is still kept in the center of the transducer array for avoiding the change of the measuring position caused by the patient's body movement. If the position is too far from the center, a warning signal is given so as to readjust the position of the pressure bladder.

3. The hand is turned toward the little finger at a small degree so that the protuberant spot of the hand bellow the thumb is far from the most protuberant spot on the volar aspect of the distal end of the radius to allow the holding strap of the pressure

bladder with a bigger diameter to closes to the wrist.
4. In order to avoid the moving of the pressure bladder in the direction of the wrist's long axis towards the hand during the bladder inflation, the difference between the diameter of the wrist joint section and that of the middle part of the forearm is eliminated. Furthermore, the sinking surface of the dorsal side of the wrist joint section due to the hand bending is filled to a regular column surface.

5. In order to reduce the pressure on the wrist and other parts when increasing the bladder pressure, the area of interface between the wrist and the wrist holding bracket as well as the bladder holding strap is made as large as possible.

6. In order to reduce the pain and numbness due to long-term continuous pressure still on one site, two pressure bladders are separately placed on both the radial and ulnar artery so that the blood pressure can be measured alternately on the two arteries. Because it is difficult to measure the blood pressure accurately on the ulna artery, the result of the blood pressure measured from the radial artery is used to calibrate the result measured from the ulnar artery. Which is to calculate the difference (D_i) between the mean blood pressure of the radial artery and the bladder pressure of ulnar artery corresponding the maximum amplitude of ulnar arterial pulse. Moreover, it is calculated that the ratio (P_i) of the ulnar arterial pulse amplitude to the maximum oscillation amplitude of the ulnar artery when the bladder pressure of ulnar artery is equal to the systolic blood pressure of the radial artery. Thus, when measuring the ulnar artery blood pressure again afterward, D_i is subtracted from the bladder pressure of ulnar artery corresponding the maximum amplitude of measured ulnar arterial pulse every time to obtain the new mean blood pressure of ulnar artery. Moreover, during the bladder pressure of ulnar artery is higher than the new mean blood pressure, the bladder pressure of ulnar artery corresponding the ulnar artery oscillation amplitude with the P_i ratio is measured to be the new systolic blood pressure. To avoid the change in D_i and P_i due to too much wrist turning, D_i and P_i should be re-calculated according above-mentioned method automatically and periodically during the long-term blood pressure measurement.

Brief description of the drawings

[0011]

FIG. 1: the simplified block diagram of the first embodiment of this invention;

FIG. 2: the perspective view of the wrist detecting assembly of the first embodiment shown in FIG. 1;

FIG. 3: the cross-section of the wrist detecting assembly as shown in FIG. 2;

FIG. 4: the cross-sectional view of the arterial pulse transducer installed in the pressure bladder, along the A-A section of the wrist detecting assembly shown in FIG. 3;

FIG. 5: the schematic illustration of the three angles between the wrist and the hand, formed by the wrist holding bracket of the wrist detecting assembly shown in FIG. 2;

FIG. 6: the schematic illustration of the method for measuring the mean blood pressure and systolic blood pressure of the first embodiment shown in FIG. 1;

FIG. 7: the simplified block diagram of the second embodiment of this invention;

FIG. 8: the schematic illustration of the method for measuring the blood pressure wave of the second embodiment;

FIG. 9: the simplified block diagram of the third embodiment of this invention;

FIG. 10: the cross-section of the wrist detecting assembly of the forth embodiment of this invention.

Detailed description of the invention

The first embodiment

[0012] The first embodiment of this invention is a method and a apparatus for non-invasive, intermittent measurement of the blood pressure on the wrist with the oscillometric method.

[0013] First, in the wrist position method for blood pressure measurement of this embodiment, shown in FIG. 5, the angle between the wrist 18 and the hand 17 is kept to the most suitable degree for measuring the blood pressure of the radial artery; it is preferably to form an angle between 100~170 degrees. Furthermore, position the turning angle of the wrist 18 relative to the forearm 19 to the most suitable degree for measuring the blood pressure of the radial artery. It is preferably for this turning angle to be 30~100 degrees. The cooperative positioning of the two angles can lower the position of the tendon and the nerves by the radial artery so that the radial artery is placed to a position nearest to the radius below it, and the bladder can press the radial artery effectively.

[0014] When measuring the blood pressure repeatedly or continuously, in order to keep the location for measuring on the wrist, as shown in FIG. 2, this invention also uses a wrist holding bracket 6 to hold the turning of the wrist 18 and the bending of the hand 17 so that when the subject moves, the position of the pressure bladder 3 and the pulse transducer 4, as well as the tendon, nerves, and radius of the wrist in relative to the radial artery always stays the same.

[0015] After the wrist position according to the above-mentioned methods, The non-invasive blood pressure measurement method of this embodiment, as shown in FIG. 1 and FIG. 6, comprise the following steps:

A. At least, placing a pressure bladder 3 and a pulse transducer array 4 on the the skin over the crossing of radial artery and the most protuberant spot on the volar aspect of the distal end of the radius 7, and keeping the position of the transducer array and the bladder relative to the site to unchanged;

B. Changing the pressure in the pressure bladder 3 within the range that the lower limit is lower than the possible mean pressure of the subject, and the upper limit is higher than the subject's possible systolic blood pressure; When the pressure of the bladder 3 changes, only the bladder wall near the wrist moves towards the wrist without the occurrence of wall tension, nor movement of the bladder in any other direction.

C. Along with the bladder pressure changing, detecting the pulse signals of the radial artery by the pulse transducer array 4 from many different positions on the wrist, and are feed to the optimal site selector 28; The amplitude of the pulse signal measured by the transducer near the radial artery is large, and the mean and systolic blood pressure corresponding the pulse signal measured on the site, where the pressure transmission is optimal, are lower. In order to find the best site on the radial artery for the optimal pressure transmission based on the above facts, first, the optimal site selector choose a column of the pulse signal with the largest amplitude during the maximum oscillation among all the columns of the pulse signals detected from those transducers arranged parallel to the radial artery; Secondly, the optimal site selector choose a channel of the pulse signal from the selected column of the pulse signal. The selected signal should possess not only maximum oscillation through the entire changing process of the bladder pressure, but also being closed to oscillation disappearance during the bladder pressure is higher than the pressure corresponding to the maximum oscillation amplitude (shown in FIG. 6), and the bladder pressures corresponding to the maximum and the disappearance of oscillation amplitude of the selected signal is the lowest. The selected signal is used as the optimal pulse signal.

D. Applying the optimal pulse signal to the non-invasive measurement of the radial artery blood pressure. In this embodiment, the optimal pulse signal is applied to the non-invasive measurement of the mean blood pressure and the systolic blood pressure with the oscillometric method.

[0016] In this embodiment, it is preferred to place the pulse transducer array 4 in the center of pressure area of the bladder 3 so that the center of pressure area of the bladder 3, where the pressure transmission is the deepest, points directly to this site for the optimal pressure transmission when the transducer, which detects the optimal pulse signal at the site for the optimal pres-

sure transmission, is placed on the center of the transducer array 4.

[0017] After selecting the optimal pulse signal, the site of the transducer in the transducer array where the optimal pulse signal is obtained will be demonstrated in the most visual way. When setting bladder 3, the position of the bladder 3 is adjusted according to the demonstration so that the transducer that detected the optimal pulse signal is positioned in the center of the transducer array 4.

[0018] When this embodiment is applied to long-term measurement of the blood pressure, automatic check should be done to make sure that the preferred transducer is at the center of the array 4. If it shifts away from the center, a warning signal should be given so as to remind the operator to readjust the position of the pressure bladder 3.

[0019] In this embodiment, the pulse transducer array 4 is fixed on the inner wall of the bladder which faces the wrist to allow the wall of the bladder to press the wrist evenly while detecting pulse signals from the radial artery.

[0020] When measuring the radial artery blood pressure, it is preferred to fix the turning angle from the central line of the hand 17 in relative to the central line of the palm side of the wrist 18 towards the little finger at 10 ~ 40 degrees, so that the protuberant spot of the hand 20 bellow the thumb does not obstruct the bladder holding strap to cling to the wrist, as shown in FIG. 5b.

[0021] In order to avoid the moving of the bladder 3 in the direction of the wrist's long axis towards the hand during the bladder inflation and to keep the bladder holding strap stably, this embodiment eliminates the difference between the diameters of the wrist joint section 17 and that of middle part of the forearm 19. Furthermore, the sinking surface of the dorsal side of the wrist joint part due to the hand bending is filled to a regular column surface.

[0022] In order to reduce the pressure from the bladder holding strap 5 to the wrist 18 and other parts during the inflation of bladder 3, the area of interface between the wrist and the wrist holding bracket 6 as well as the bladder holding strap 5 is made as large as possible.

[0023] As shown in FIG. 1, the apparatus based on the method above-mentioned in this embodiment comprising three parts: Part I is a wrist detecting assembly 1 for applying the external pressure and detecting the arterial pulse; Part II is a pulse signal processing device 1 for selecting the optimal pulse signal from the radial artery pulse signals detected by the wrist detecting assembly 1; and Part III is a pressure feeding-measuring system 2 to feed the pressure to bladder 3 and measure both the bladder pressure and the radial arterial pulse signals for the blood pressure measurement of the radial artery.

[0024] First, Part I - the wrist detecting assembly 1 will be described. As shown in FIG. 2 and FIG. 3, This embodiment is to measure the blood pressure of the radial

artery by applying the external pressure to the radial artery 7 and detecting radial arterial pulse in wrist. the wrist detecting assembly 1 includes four parts: the pressure bladder 3, the arterial pulse transducer 4, the bladder holding strap 5, and the wrist holding bracket 6.

[0025] As shown in FIG. 2 and FIG. 3, the radial artery pressure bladder 3 of this embodiment is a flat, round, air-filled bladder. In order to ensure that the bladder pressure can be sufficiently transmitted to the depth of the radial artery 7, on the one hand, the position of the bladder 3 should enable its center to be aligned to the radial artery 7 at the most protuberant spot on the volar aspect of the distal end of the radius; on the other hand, the diameter of the bladder 3 should be large enough. However, if the diameter is too large, the bladder 3 will press another ulnar artery 9 and some other vein synchronously, this diameter can be selected as $1/3 \sim 3/5$ of the wrist diameter (e.g. about 30 mm for adult). In addition, to ensure that the bladder 3 won't produce circumferential tension within its walls due to inflation after the air is filled so as to effectively press the radial artery 7, the inner wall 10 of the bladder 3 which faces the wrist is made with transparent, resilient membrane shaped to upheave towards the wrist. The wall along the circumference and the outer wall of the bladder 3 are made of rigid material.

[0026] Radial arterial pulse transducer 4 is an array of reflective photoelectric transducers. As shown in FIG. 3, there is a very complicated, nonhomogeneous structure inside the wrist. Take the area around the radial artery for instance, apart from the radius 8 below the artery 7, there are several tendons 11 and nerves 12 with high rigidity in the soft tissue on both sides of the radial artery, these tendons and nerves can block the pressure transmission in the soft tissue. According to the principles of mechanics, the site where the bladder pressure can be transmitted effectively to the radial artery 7 so as to accurately measure the blood pressure of the radial artery is the site near the skin and radius 8, but far from the tendons 11 and nerves 12. However, in fact, in the wrist (see FIG. 1, FIG. 3), the depth and position of the radial artery 7 itself, as well as the shape and position of the tendons 11 and radius 8, change with the position along the axial direction of the wrist. Especially the shape of the cross section of the radius 8 at the most protuberant spot on the volar aspect of the distal end of the radius is not regular and changes with different people. Obviously, to locate the above-mentioned site to accurately measure the blood pressure of the radial artery, a transducers array of 4 must be used to detecting the arterial pulse signals meticulously from many sites for comparison and analysis. In order to place the transducers 4 with the above-mentioned pressure bladder 3 onto the wrist while do not obstruct the the bladder wall to evenly press the wrist, this transducer array 4 is mounted within the above-mentioned bladder 3. As shown in FIG. 4, in this embodiment, the transducer array 4 consists of ten infrared light emitting diodes 13 and fifteen

phototransistors 14, among which the fifteen phototransistors 14 form a rectangle array. This array has three column phototransistors parallel to the radial artery 7, with each column consisting five row phototransistors. There is a clearance in between both the columns and in between the rows. The ten infrared light emitting diodes 13 are arranged around the four sides of the rectangle array, with clearance between the diodes and the four sides of the array. These emitting diodes 13 and phototransistors 14 are fixed to the inside of the inner wall 10, made of semi-transparent membrane, of the above-mentioned bladder 3. When fixing them, the light emitting surface of the emitting diodes 13 and the light receiving surface of the phototransistors 14 should face the inside of the inner membrane wall 10, and the center of the phototransistor array should point to the center of the inner membrane wall 10. In addition, to avoid the phototransistors 14 are affected by the light from the light emitting diodes 13 and the environment light, a layer of shading sheet 15 of good extensibility (black sponge sheet for instance) is glued between the light emitting diodes 13 and the phototransistor array, as well as around the whole phototransistor array. When detecting the pulse of the radial artery 7 with this phototransistor, the infrared light is emitted by the ten light emitting diodes 13 from ten different sites, passing the inner semi-transparent membrane wall 10, into the wrist. Because the intensity of the light reflected into the phototransistors 14 change along with the radial arterial volume caused by the periodical change of its blood pressure, so as to change the output current of the phototransistors 14, the volume change (pulse) of the radial artery 7 can be transformed into the fifteen channel of radial arterial pulse signals to output.

[0027] Bladder holding strap 5 is used to hold the pressure bladder 3 installed the above-mentioned pulse transducer. To simplify the structure, this embodiment integrates the bladder 3 and the holding strap 5 into one wrist detecting assembly. This is done by using a strap with certain thickness and rigidity and, processing a flat, circular delve whose diameter is the same as the diameter of the bladder 3 on the wrist side of said strap in a position corresponding to radial artery, and then the edge of the inner bladder wall 10 is glued to the edge of the delve of strap 5 to form the above-mentioned bladder 3 by integrating the inner bladder wall 10 of membrane and the delve. In order to avoid the outer wall of the bladder moving towards the outside caused by bladder inflation, the strap 5 should be made with non-extensible material, and the apparatus for fixing its two ends should also be non-extensible. In this embodiment, the two ends of the strap 5 are fixed on the backside of the wrist holding bracket 6 with nylon agraffe 16. Meanwhile, to prevent the bladder 3 from moving along the circumference during the bladder inflation, the strap 5 (at least in the part surround the palmar side of wrist from the dorsal side of the radius 8 to the palmar side of the ulnar) should be rigid. This is because that the blad-

der moving along the circumference is due to that the cross section of the wrist is a ellipse, and bladder 3 which is a local pressure bladder, is placed right on the connection of the arc of the two different curvatures. This will cause imbalance in the circumferential component of the pull force in the bladder holding strap 5 of the two sides of the bladder, so as to cause the bladder 3 to move along the circumference. In addition, the strap 5 should possess appreciably elasticity so that when the diameter of the wrist is reduced due to long-term, continuous pressure, its resilient capability can still enable the bladder 3 to wrap tightly onto the wrist without any movement. On the other hand, to guarantee that only the radial artery 7 to be measured is sufficiently pressured by bladder 3, and the pressure from the strap 5 to the wrist and other parts is reduced as much as possible, the effective area of the interface between the strap 5 and the wrist should be as big as possible. To do this, the strap width should be as wide as possible (larger than 50 mm for normal adults), and the side of the strap facing the wrist 18 and the hand 17 should be shaped to match with the scraggly shape of dorsal side of the wrist and the hand.

[0028] The wrist holding bracket 6 is a curved board made of material with high rigidity. Its length and width should cover the entire back of the hand, the dorsal side of the wrist and the dorsal side of the forearm near the elbow joint. The wrist holding bracket 6 has three functions. The first function is to keep the angle between the wrist 18 and the hand 17 and the turning angle of the wrist 18 relative to the middle of forearm 19 to the most suitable degree for measuring the blood pressure of the radial artery. At the same time, it limits the turning of the wrist 18 and the bending of the hand 17 so that when the subject moves, the position of the pressure bladder 3 and the pulse transducer 4, as well as the tendon 11, nerves 12, and radius 8 in the wrist in relative to the radial artery 7 stays the same. As shown in FIG. 5(a) and FIG. 5(c), the shape of the wrist holding bracket 6 should make it should also form an inward turning angle of 30 ~ 100 degrees from the palmar side of the wrist 18 to the palmar side of the forearm near the elbow joint. To ensure the two angles can lower the position of the tendons 11 and nerves 12 nearby the radial artery 7 and cause the radial artery 7 to reach close to the radius 8, and also make the bladder 3 to effectively press the radial artery 7. Also, as shown in FIG. 5(b), the shape of holder 6 should also enable the forming of the turning angle from the central line of the hand 17 in relative to the central line of the palmar side of the wrist 18 towards the little finger at 10~40 degrees, so that the protuberant spot of the hand 20 below the thumb does not obstruct the holding strap 5, integrated the bladder with a bigger diameter, to closes to the wrist. The second function of the wrist holding bracket 6 is to improve the stability of the bladder holding strap 5. Considering that the reason of the bladder 3 moving in the direction of the wrist's long axis towards the hand during the bladder

inflation is that the diameter of the middle part of the forearm 19 is larger than the that of the wrist joint section 17 so that the component of forces towards the hand 17 is produced on the outer wall of the bladder 3 during bladder pressure, therefore, as shown in FIG. 5(a), the thickness of the holder 6 in the part connecting the dorsal side of the hand 17 and the dorsal side of the wrist 18 should be increased, so as to eliminate the difference between the diameters of the wrist joint section 17 and middle part of the forearm 19. In addition, the increase in thickness in the connecting part of the wrist holding bracket can also increase the intensity when the holder is used to hold the hand 17. Moreover, the sinking surface of the dorsal side of wrist joint part due to the hand bending towards the dorsal side is filled to a regular column surface. The third function of the wrist holding bracket 6 is to disperse the pressure of the bladder holding strap 5 on the dorsal side of the wrist. For this reason, the inside of the wrist holding bracket 6 should be shaped to matches well with the scraggly shape of the dorsal side of the wrist 18, and it is preferred to prepare several kinds of holders for different shapes and widths of the wrist. Also, to avoid causing discomfort to the subject due to the hardness of the holder 6, a thin layer of soft cushion 21 should be glued to the inner side of the holder 6. In addition, to tie the subject's hand 17, the wrist 18, and the forearm 19 inside the wrist holding bracket, several small straps with nylon agraffes at the ends should be fixed onto the wrist holding bracket 6.

[0029] The operational process of the apparatus for non-invasive intermittent measurement of the radial artery blood pressure in this embodiment is:

[0030] As shown in FIG. 1, the fifteen outputs of the pulse transducer array 4 of the wrist detecting assembly 1 are connected separately with the fifteen inputs of the multi-channels of amplifier and filter 23 of the pulse signal processing device 1. At the same time, the air tubing of the radial arterial pressure bladder 3 is connected to the pressure output of the voltage/pressure converter 24 of the pressure feeding-measuring system 2, and the pressure input of the pressure transducer 25, which is connected to the pressure signal amplifier 26.

[0031] When setting the wrist detecting assembly, first, the hand 17, wrist 18 and forearm 19 of subject are fixed into the wrist holding bracket 6 of the wrist detecting assembly 1. Then, after pointing the center of the bladder 3 of the wrist detecting assembly 1 directly to the radial artery 7 on the most protuberant spot on the volar aspect of the distal end of the radius, wrap the bladder holding strap 5 to the wrist 18. Lastly, fix the two ends of the holding strap to the wrist holding bracket 6 with nylon agraffes 16.

[0032] When the blood pressure measurement begins, the bladder pressure setting circuit 27 of the pressure feeding-measuring system 2 starts to adjust automatically the input voltage of the voltage/pressure converter 24, so as to inflate the bladder 3 of the wrist detecting assembly 1 to apply the external pressure to the

radial artery 7. Meanwhile, the pulse transducer array 4 of the wrist detecting assembly 1 detects the radial arterial pulse signals. These pulse signals are fed to the pulse signal processing device 1 to amplify and filter them, and then are fed to the optimal site selector 28. Due to the difference in positions, the amplitudes and the envelope shapes of the radial arterial pulse signals detected from the fifteen sites of the wrist are all different from each other, and the maximum and disappearance of radial arterial pulse amplitude measured in some sites may not be found. Obviously, the amplitude of the pulse signal measured by the transducer near the radial artery is larger, and the mean and systolic blood pressure corresponding to the pulse signal measured on the site with the accurate pressure transmission is lower. Therefore, the optimal site selecting method comprise: first, choosing a column of the pulse signal with the largest amplitude during the maximum oscillation among all the columns of the pulse signals detected from those transducers arranged parallel to the radial artery in the array; secondly, choosing a channel of the pulse signal from the selected columns of the pulse signals, said selected signal possessing not only maximum oscillation through the entire pressure changing process of the pressure bladder, but also being closed to disappearance during the bladder pressure is higher than the pressure corresponding to the maximum oscillation, and the bladder pressures corresponding to the maximum and the disappearance of oscillation of the selected signal being the lowest; finally, said selected signal being used as the optimal pulse signal.

[0033] The selected optimal pulse signal is fed to a pulse amplitude detecting circuit 29 to find the maximum and the disappearance of their oscillation amplitude. According to the principles of the oscillometric method, the bladder pressure corresponding to the maximum and appearance of the oscillation amplitude will respectively equal the mean blood pressure and the systolic blood pressure of the artery to be measured. Therefore, when the maximum and disappearance of oscillation amplitude is found by the amplitude detecting circuit 29, a control signal is given so that the bladder pressure at the above-mentioned two moments are measured and are output by a pressure value output circuit 30; thus, the measured results of the mean blood pressure and the systolic pressure are obtained, and the diastolic blood pressure can be obtained by calculating according to the diastolic blood pressure = $(3 \times \text{mean blood pressure} - \text{systolic blood pressure}) / 2$ by the diastolic blood pressure calculator 31.

[0034] On the other hand, for the convenience for the location of the pressure bladder, the selected optimal pulse signal is also used for controlling a transducer position display. This display can indicate the exact position of the transducer measured the optimal pulse signal in the transducer array in the most visual way (for example, drawing the transducer array) on the display screen. When setting the bladder 3, the position of the

bladder 3 is adjusted according to the display so that the transducer detected the optimal pulse signal is positioned in the center of the transducer array. In this embodiment, there is also a optimal site warning circuit 38. When setting the bladder or during long-term measurement of the blood pressure, if the subject's wrist turns significantly (even though the wrist holding bracket 6 can limit the turning of the wrist 18 in relative to the forearm 19, the wrist can still turn to a certain extent) so that if the transducer is too far from the center of the transducer array, the transducer position warning circuit 38 will give warning signal to remind the operator to readjust the position of the pressure bladder 3. Since the optimal pulse signal is selected in every measurement, it is ensured that the measurement is done at the optimal site every time.

[0035] This embodiment is especially suitable for clinic or family monitoring of long-term blood pressure of the patient whose blood pressure changes very smoothly (for example, after a surgery, or recovering from a treatment).

The second embodiment

[0036] The second embodiment of this invention is a method and a apparatus for non-invasive continuous measurement of radial artery blood pressure on the wrist with the vascular unloading method. As shown in FIG. 7, the wrist position method and the optimal pulse selecting method in this embodiment are both the same as those used in the first embodiment. Their main difference is that the selected optimal pulse signal is used for non-invasive continuous measurement of the radial artery blood pressure wave with the vascular unloading method. Since the vascular unloading method is a known technique, its operation process will be described in detail later.

[0037] The apparatus of this embodiment is shown in FIG. 7. The wrist detecting assembly 1 and the pulse signal processing device 1 can be the same as those used in the first embodiment. The wrist holding bracket and bladder holding strap is also the same as in the first embodiment, so it won't be repeated here. In this embodiment, the main difference from the first embodiment is that the output of the optimal site selector 28 of the pressure feeding-measuring system 32 is not used to control the pressure value output circuit to read the pressure of the bladder 3, but is connected with the input of the voltage/pressure converter, through a comparator and a servo amplifier, to form a closed-loop feedback control system to control the pressure change of the bladder 3.

[0038] Before continuous measuring the blood pressure with this method and apparatus, in order to find and memorize the volume of the radial artery 7 at its unloading state, the pressure feeding-measuring system 2 first turns the operational state switch to the "open-loop". As shown in FIG. 8, under the open-loop operational state,

like the oscillometric method, the bladder pressure setting circuit 27 automatically adjusts the voltage feed to the voltage/pressure converter so that the bladder 3 will start the pressure to radial artery 7. At the same time, the pulse signals of the radial artery 7 are detected by the pulse transducer array 4 from fifteen sites of the wrist, and are amplified, filtered, then are fed to the optimal site selector 28. The selected optimal pulse signal is fed to the amplitude detecting circuit 34. When the maximum oscillation amplitude is detected, i.e. when it has been identified that the radial artery 7 is already pulsating around its unloading volume, along with the periodical change of the inner blood pressure, the system stops the bladder pressure setting circuit 27 from adjusting the pressure of the bladder 3, and enable the unloading volume memory 35 to memorize the average of the radial artery pulse wave (D.C. component of the pulse signal) as the unloading volume V_0 of subject's radial artery.

[0039] Then, the pressure feeding-measuring system 32 automatically turns the operational state switch to the "close-loop", by a comparing circuit 36, the pulse signal near the unloading volume of the radial artery 7 detected by the pulse transducer is subtracted from the unloading volume V_0 memorized by the unloading volume memory 35. The gain of the servo amplifier 37 is increased steadily, so that the obtained difference (e.g. the pulsation of the radial artery pulse wave) is amplified and phase compensated, and fed to the voltage/pressure converter 24 to control the pressure of bladder 3 to apply further the external pressure whose wave is the same as the blood pressure wave to radial artery 7, so that the amplitude of the radial arterial pulse is reduced, as shown in the beginning section of the close-loop state in FIG. 8 (to view easily, the waves in the close-loop state is extended along the time axis). Obviously, when the gain of the servo amplifier 37 is adjusted to where the bladder pressure to the radial artery 7 is completely the same as the blood pressure wave of the radial artery not only in the shape but also in the amplitude, i.e. when the force on both the inside and outside of the vessel wall of the radial artery 7 is made to reach a dynamic balance, as shown in the section after the close-loop state in FIG. 8, the vessel wall of the radial artery 7 will not pulsate with the periodical change of the blood pressure, and the blood vessel volume will be maintained on the unloading volume V_0 . Therefore, under the close-loop operation state, if the moment when the pulse amplitude of the radial artery 7 become to near zero is found during steadily increasing the gain of the servo amplifier 37, it is assured that from the moment, the pressure in the pressure bladder 3 will equal the blood pressure of the radial artery 7 at any time. Thus, the non-invasive continuous measurement of the radial artery blood pressure wave is obtained by measuring continuously the pressure of the pressure bladder 3 with a pressure transducer 25 that is connected to the pressure bladder 3.

[0040] This embodiment is especially suitable for the

clinical monitoring of the patients whose blood pressure changes very fast so as to need long-term, continuous measurement of beat-by-beat blood pressure (for example, patients under anaesthesia, surgery, or emergent care).

The third embodiment

[0041] This embodiment is a method and a apparatus for both intermittent measurement of blood pressure and continuous measurement of the blood pressure wave on the radial artery of wrist, as shown in FIG. 10. In this embodiment, the wrist position method and the optimal site selecting method are both the same as in the first embodiment. Their main difference is that the selected optimal pulse signals are used exchangeably for non-invasive measurement of the mean and the systolic blood pressure with the oscillometric method and non-invasive measurement of the continuous blood pressure wave with the vascular unloading method.

[0042] The apparatus of this embodiment also comprises a wrist detecting assembly 1 and a pressure feeding-measuring system 2. Most parts of the wrist detecting assembly and the pressure feeding-measuring system are the same as the above two embodiments. The difference is that, in order to both measure intermittently the blood pressure and measure continuously the blood pressure wave, as shown in FIG. 9, the pressure feeding-measuring system (parts 29, 30, 31 for controlling and reading the bladder pressure in FIG. 1) of the first embodiment and the pressure feeding-measuring system (parts 34, 35, 36, and 37 for controlling the bladder pressure change in FIG. 7) of the second embodiment are exchanged through a "intermittent measurement-continuous measurement" function switching device 39. Since this switch is simple, it won't be further discussed here.

[0043] For patients whose blood pressure changes sometimes smoothly and sometimes fast, this embodiment can make it possible to choose freely the measuring intervals in a range from zero to infinity according to the patient's conditions for long-term monitoring of the blood pressure in clinic and family.

The forth embodiment

[0044] The forth embodiment of this invention is the intermittent and/or continuous measurement of the blood pressure alternately on radial artery 7 and ulnar artery 9. The wrist position method and optimal site selecting method are both the same as the above three embodiments. The main difference is that there are two pressure bladder, i.e. bladder 3 and bladder 3', which are placed separately on radial artery 7 and ulnar artery 9 to measure blood pressure alternately.

[0045] In this embodiment, the pulse transducer installed in radial arterial pressure bladder 3 is the same as the transducer array 4 used in the above three em-

bodiments. However, the transducer installed in ulnar arterial pressure bladder 3' can be only more than two reflective photoelectric sensors connected parallel with each other.

[0046] In this embodiment, the result of the blood pressure measured on the radial artery 7 should be used to calibrate the result measured on the ulnar artery. That is, calculating the difference (D_i) between the mean blood pressure measured from the radial artery 7 and the bladder pressure of ulnar artery 9 corresponding to the maximum pulse amplitude of ulnar arterial pulse, and calculating the ratio (P_i) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the bladder pressure of ulnar artery is equal to the systolic blood pressure measured from the radial artery; so that, each time thereafter, the new mean blood pressure of ulnar artery can be obtained by subtracting D_i from the bladder pressure of ulnar artery corresponding the maximum amplitude of measured ulnar arterial pulse, and the new systolic blood pressure of ulnar artery can also be obtained by measuring the bladder pressure of ulnar artery when the ulnar arterial pulse amplitude with the P_i ratio to its maximum amplitude during the bladder pressure of ulnar artery is higher than the new mean blood pressure of ulnar artery.

[0047] When calibrating the result measured on the ulnar artery 9, the air tubing of the pressure bladders 3 and pressure bladders 3' can be connected to measure the blood pressure simultaneously both on radial artery 7 and ulnar artery 9 with the oscillometric method.

[0048] Or, when calibrating the result measured on the ulnar artery 9, the measurement of the blood pressure both on the radial artery 7 and ulnar artery 9 can be done immediately one after the other.

[0049] During long-term, continuous measurement of the blood pressure with the method of this embodiment, D_i and P_i should be recalculated according above-mentioned method automatically and periodically.

[0050] To apply the methods of this embodiment, the apparatus used by this embodiment also comprises a wrist detecting assembly 1 which basically the same as in the first embodiment, but as shown in FIG. 10, a pressure bladder 3' to press the ulnar artery is placed opposite to the existing radial artery pressure bladder 3 on the bladder holding strap 5, and also a pulse transducer for detecting the ulnar artery pulsation is installed in the bladder 3'. Also, it can use any of the two independent pressure feeding-measuring systems used in the above three embodiments, by using a switching device, to measure the intermittent or continuous blood pressure of radial artery or ulnar artery alternately.

[0051] In this embodiment, the radial artery pressure bladder and the radial arterial pulse transducer should have the same structure as that used in the first embodiment so as to accurately measure the blood pressure of the radial artery like the first embodiment. Ulnar artery pressure bladder 3' can be the same structure as in the first embodiment, but the ulnar arterial pulse transducer

does not need to use a photoelectric sensor array as complicated as the radial arterial pulse transducer. This is because, as shown in FIG. 3, the position of ulnar artery 9 is considerably deep, and there are tendons 11 in between ulnar artery and skin, so the bladder pressure cannot be sufficiently transmitted to the ulnar artery 9; therefore, it is difficult to accurately measure the blood pressure of the ulnar artery on any site of wrist. Usually, within the normal changing range of ulnar artery bladder pressure, the maximum oscillation amplitude can be detected on the ulnar artery, but the disappearance of oscillation amplitude cannot be detected, and the bladder pressure corresponding to the maximum oscillation amplitude of ulnar artery is usually higher than the mean blood pressure of the ulnar artery. However, to find the ulnar artery conveniently, it is preferred to place more than two photoelectric sensors of parallel-connection along the circumference of the wrist over the ulnar artery, so that, when applying the photoelectric sensors of parallel connection, only one channel amplifier and filter for the ulnar arterial pulse signals is required, and the optimal site selector can be omitted.

[0052] Usually, for a given wrist, the radial artery blood pressure is the same as the blood pressure of ulnar artery, and if the wrist does not turn too much, the difference between the pressure in the ulnar artery pressure bladder 3' and the pressure transmitted to the ulnar artery 9 is constant. Therefore, the result of the blood pressure measurement on the radial artery can be used as standard to calibrate the result of the blood pressure measurement on the ulnar artery. When calibrating, the tubing of the two pressure bladders 3 and 3' can be connected each other to measure the blood pressure simultaneously both on radial artery 7 and ulnar artery 9 with the oscillometric method. Then, calculating the difference (D_i) between the mean blood pressure measured from the radial artery 7 and the bladder pressure of ulnar artery 9 corresponding to the maximum pulse amplitude of ulnar arterial pulse, and calculating the ratio (P_i) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the bladder pressure of ulnar artery is equal to the systolic blood pressure measured from the radial artery; so that, each time thereafter, the new mean blood pressure of ulnar artery can be obtained by subtracting D_i from the bladder pressure of ulnar artery corresponding the maximum amplitude of measured ulnar arterial pulse, and the new systolic blood pressure of ulnar artery can also be obtained by measuring the bladder pressure of ulnar artery when the ulnar arterial pulse amplitude with the P_i ratio to its maximum amplitude during the bladder pressure of ulnar artery is higher than the new mean blood pressure of ulnar artery. To avoid the change in D_i and P_i due to too much turning of the subject's wrist, during long-term, continuous measurement of the blood pressure with the method of this embodiment, D_i and P_i should be recalculated according above-mentioned method automatically and periodically.

[0053] In this embodiment, in order to simplify the circuit, the other parts (except amplifier and filter, optimal site selector and the amplitude detecting circuit) of the two independent pressure feeding-measuring systems, respectively for the blood pressure measurement of radial artery and ulnar artery, can be shared. Furthermore, it can be done to use one pressure feeding-measuring system for both radial artery and ulnar artery blood pressure measurement, and when measuring any one of the radial artery and ulnar artery, a switching device is used to connect the pressure feeding-measuring system with one of the two bladder's tubes and the pulse transducers alternately. However, since such simplification make it become impossible to obtain the blood pressure on both arteries simultaneously during one course of blood pressure measurement, when calibrating the result of the blood pressure measurement on the ulnar artery, the measurement of the blood pressure on radial artery and the ulnar artery should be done separately one after the other. The calibration method is the same as the above, however, the result of the radial artery blood pressure measurement, used as the standard, is not obtained simultaneously with the ulnar artery blood pressure measurement, but is the result of the blood pressure measurement next to the ulnar artery blood pressure measurement.

[0054] Since pain and numbness caused by long-term, continuous pressure on one site can be avoided by the use of two arteries alternately, this embodiment can prolong considerably the time for repeated and continuous blood pressure measurement.

The fifth embodiment

[0055] The method of the blood pressure measurement in the fifth embodiment is the same the above embodiments.

[0056] The difference from the above embodiments is that, in the apparatus of this embodiment, the pressure transducer, voltage/pressure converter of the pressure feeding-measuring system, even the whole pressure feeding-measuring system, are integrated with the wrist detecting assembly, so that these parts are made into a whole. The integration can reduce the connecting cables and tubing during the measurement and is more convenient for clinic application. Especially, for continuous blood pressure measurement with the vascular unloading method, the integration can greatly increase the speed of the pressure feedback control so that the measurement of the blood pressure wave is much more precise.

The sixth embodiment

[0057] The sixth embodiment of this invention is to integrate above any non-invasive wrist blood pressure measurement apparatus, described in the above five embodiments, with the measurement device of other

physiological parameters (e.g., electrocardiogram, respiration, and body temperature) to form a multiple vital signal monitor.

5 The seventh embodiment

[0058] The seventh embodiment of this invention is to connect any non-invasive wrist blood pressure measurement apparatus, described in the above six embodiments, with the data recording device (e.g., tape recorder, integrate circuit memory, etc.), or make them into a whole and miniaturize it to form a portable, long-term blood pressure monitoring device.

15 The eighth embodiment

[0059] The eighth embodiment of this invention is to connect any non-invasive wrist blood pressure measurement apparatus, described in the above seven embodiments, with wired or radio communications (e.g., radio transmitter, wired phone or radiophone, etc.) to form a long distance blood pressure monitoring and controlling web to transmit measurement results to and receive medical instructions from medical institutions.

25 The ninth embodiment

[0060] The wrist position method, optimal site selecting method, and blood pressure measurement method of this embodiment are the same as in the first embodiment.

[0061] However, the apparatus of the ninth embodiment is simplified and improved based on the first embodiment. In this embodiment, the wrist holding bracket 6 is omitted. To ensure the correct wrist position, during blood pressure measurement, the subject keeps his/her own wrist 18 and the hand 17 to fixedly according to the instructions of the apparatus, and keeps the turning angle of the wrist 18 in relative to the forearm and the angle between the hand 17 and the wrist 18 at a degree most suitable for measuring the blood pressure of the radial artery. Then the bladder holding strap is correctly wrapped and fixed according to the position shown on the optimal pulse transducer so that the mean blood pressure, systolic blood pressure, and distolic blood pressure of the radial artery are measured.

[0062] A portable wrist blood pressure meter, which is convenient for daily family use of measuring blood pressure or monitoring the result of treatment for hypertension patient, as well as for clinical physical examination, can be made according to this embodiment.

[0063] The above embodiments are described only for illustrating this invention, but not for limiting this invention. This invention can also have many other embodiments and improvement plans. For example, in the above four embodiments, we used the oscillometric method for intermittent blood pressure measurement and the vascular unloading method for continuous blood

pressure measurement. In both, the fact of whether or not the subject's arterial pulse oscillation amplitude reaches the maximum is used as the criterion to judge if the subject's artery blood pressure is at its unloading state, air pressure control is used to control the external pressure on the artery to be measured, and the photo-electric sensor is used to detect arterial pulse. In fact, other criterions, such as the shape of the pulse waveform or the change in the level of the base line, the change in the oscillation amplitude of the small vibration wave added artificially to the pulse wave, and the change in the speed of blood flow in the artery being measured, can be used to judge the unloading state of the subject's artery. In addition, hydraulic pressure control can also be used to control the external pressure on the subject's artery, and other types of volume sensitive means can be used for measuring the arterial pulse.

Claims

1. A wrist position method for non-invasive blood pressure measurement, at least placing an arterial pulse transducer on the skin over the radial artery of the wrist to detect pulse signal of radial artery, wherein at least the angle between the hand and the wrist is kept to the most suitable degree for measuring the blood pressure of the radial artery, such an angle is capable of lowering the position of the tendon and causing the radial artery to reach close to the radius.
2. A method as defined in claim 1 wherein said the suitable angle between the dorsal side of the hand and the dorsal side of the wrist is preferably a angle of 100 - 170 degrees when measuring blood pressure on the radial artery.
3. A method as defined in claim 1 wherein the turning angle of the wrist relative to the middle part of the forearm is kept to the most suitable degree for measuring the blood pressure of the radial artery, such an angle can also cause the radial artery to reach close to the radius.
4. A method as defined in claim 3 wherein said the turning angle of the wrist relative to the middle part of the forearm is preferably a turning angle of 30 - 100 degrees formed by turning inward palm side of the wrist relative to the part of the forearm close to the elbow joint.
5. A non-invasive blood pressure measurement method with the wrist position method as defined in claim 1, comprising the steps of,

(1) placing at least a pressure bladder and an arterial pulse transducer array on the skin over

the crossing of radial artery and the most protuberant spot on the volar aspect of the distal end of the radius, and keeping the position of said transducer and pressure bladder relative to the site to remain unchanged;

(2) controlling the change of pressure of the pressure bladder within the range between the lower limit below the possible mean blood pressure and the upper limit above the possible systolic blood pressure of the subject;

(3) detecting the pulse signals of the radial artery by said arterial pulse transducer array from various sites of the wrist along with the pressure change of said pressure bladder, and feeding the pulse signals to a optimal pulse selector to find the optimal measuring site with the optimal pressure transmission on the wrist; due to the amplitude of the pulse signal measured by the transducer near the radial artery being large, and the mean and systolic blood pressure corresponding to the pulse signal measured on the site with the accurate pressure transmission being lower, the optimal site selecting method comprise: first, choosing a column of the pulse signal with the largest amplitude during the maximum oscillation among all the columns of the pulse signals detected from those transducers arranged parallel to the radial artery in the array; secondly, choosing a channel of the pulse signal from the selected columns of the pulse signals, said selected signal possessing not only maximum oscillation through the entire pressure changing process of the pressure bladder, but also being closed to disappearance during the bladder pressure is higher than the pressure corresponding to the maximum oscillation, and the bladder pressures corresponding to the maximum and the disappearance of oscillation of the selected signal being the lowest; finally, said selected signal being used as the optimal pulse signal;

(4) employing said optimal pulse signal to non-invasive blood pressure measurement.

6. A method as defined in claim 5 wherein said pulse transducer array is preferably placed at the center of the pressure area of said pressure bladder so that, when the transducer measured the optimal pulse signal is at the center of said pulse transducer array, the site with accurate pressure transmission can correspond to said pressure area center where the pressure can be transmitted most deeply.
7. A method as defined in claim 6 wherein the position of the transducer measured the optimal pulse signal in the array is displayed in the most visual way; and when setting said pressure bladder, the position of said pressure bladder is adjusted according the dis-

play to make the transducer measured the optimal pulse signal to be at the center of said pulse transducer array.

8. A method as defined in claim 7 wherein it is detected automatically whether the transducer measured the optimal pulse signal is at the center of said pulse transducer array or not, and if the distortion is too far from said center, a warning signal is given for repositioning of said pressure bladder.
9. A method as defined in claim 5 wherein said pulse transducer array is preferably placed on the inside of the wall of said pressure bladder which faces the wrist, so that said pressure bladder can press evenly the surface of the wrist.
10. A method as defined in claim 5 wherein the hand is slightly turned towards the little finger to form an angle of 10 - 40 degrees between the centerline of the hand and the centerline of the palm side of the wrist, so that the protuberant spot at the end of the root segment below the thumb does not obstruct the bladder holding strap to cling to the wrist.
11. A method as defined in claim 5 wherein the difference between the diameters of the wrist joint section and that of middle part of the forearm is eliminated, and the sinking surface of the wrist joint part due to the hand bending is filled to a regular column surface to avoid said pressure bladder shifting towards the hand along the long axis of the wrist during the inflation of said pressure bladder.
12. A method as defined in claim 5 wherein the interface area between the wrist and the holding devices for both the pressure bladder and the wrist is made to be as large as possible, so as to minimize the pressure from the holding devices on to other areas of the wrist during the inflation of said pressure bladder.
13. A method as defined in claim 5 wherein said optimal pulse signal is used for non-invasive intermittent measurement of the mean and systolic blood pressure of the radial artery with volume oscillometric method.
14. A method as defined in claim 5 wherein said optimal pulse signal is used for non-invasive continuous measurement of the blood pressure wave of the radial artery with volume compensation method.
15. A method as defined in claim 5 wherein said optimal pulse signal is used alternately for non-invasive intermittent measurement of the mean and systolic blood pressure of the radial artery with volume oscillometric method, and non-invasive continuous

measurement of the blood pressure wave of the radial artery with volume compensation method.

16. A method as defined in claim 5 wherein said pressure bladder and arterial pulse transducer array are placed on the radial artery and the ulnar artery respectively so that the blood pressure can be alternately measured from the two arteries.
17. A method as defined in claim 16 wherein said ulnar arterial pulse transducer can also be parallel-connected photoelectric sensors, and it is preferred to place more than two such parallel-connected photoelectric sensors vertical to the ulnar artery, within the pressure area of the ulnar arterial pressure bladder.
18. A method as defined in claim 16 wherein the result of the blood pressure measured from the radial artery is used as the standard for calibrating the result measured from the ulnar artery.
19. A method as defined in claim 16 wherein said method using the result of blood pressure measured from radial artery to calibrate the result measured from the ulnar artery comprise: calculating the difference (Di) between the mean blood pressure measured from the radial artery and the bladder pressure of ulnar artery corresponding to the maximum pulse amplitude of ulnar arterial pulse, and calculating the ratio (Pi) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the bladder pressure of ulnar artery is equal to the systolic blood pressure measured from the radial artery; so that, each time thereafter, the new mean blood pressure of ulnar artery can be obtained by subtracting Di from the bladder pressure of ulnar artery corresponding the maximum amplitude of measured ulnar arterial pulse, and the new systolic blood pressure of ulnar artery can also be obtained by measuring the bladder pressure of ulnar artery when the ulnar arterial pulse amplitude with the Pi ratio to its maximum amplitude during the bladder pressure of ulnar artery is higher than the new mean blood pressure of ulnar artery.
20. A method as defined in claim 19 wherein, when using the result of blood pressure measured from radial artery to calibrate the result measured from the ulnar artery, said two pressure bladders are interconnected by their tubing to measure the blood pressure from both the radial artery and the ulnar artery simultaneously with volume oscillometric method.
21. A method as defined in claim 19 wherein, when using the blood pressure measured from radial artery

to calibrate the blood pressure measured from the ulnar artery, said procedures of measuring blood pressure from the radial artery and from the ulnar artery are separated one after the other.

22. A method as defined in claim 16 or claim 18 or claim 19 wherein said DI and PI are recalculated automatically during a long-term, continuous measurement of blood pressure.

23. A method as defined in claim 5 wherein other criterion, such as the changes in the shape or the base-line level of the pulse waveform, the changes in the amplitude of minor oscillation added artificially on the pulse waveform, the change in the speed of the blood flow, etc. can be used to evaluate the unloading state of the artery to be measured, and hydraulic pressure can also be used to control the external pressure of the artery, and also other types of volume sensitive means can be used for measuring the arterial pulse.

24. A wrist detecting assembly for non-invasive blood pressure measurement, at least comprising a pressure bladder placed on the skin over either the radial artery or the ulnar artery by a holding means, wherein at least an arterial pulse transducer array is placed within the pressure area of said pressure bladder.

25. A device as defined in claim 24 wherein the shape of the pressure area of said pressure bladder is preferably circular, the diameter of which should be $1/3 - 3/5$ of that of the wrist, and the wall of said pressure bladder which closes to the wrist should be made with resilient membrane shaped to shaped to upheave towards the wrist, and the wall along the circumference and the outer wall of said pressure bladder should be made of rigid material.

26. A device as defined in claim 24 wherein the pulse transducer in said arterial pulse transducer array is preferably the reflective photoelectric transducer that consists of light emitting devices and photoelectric devices, and the preferred structure of which should be composed of a rectangle array of photoelectric devices arranged close to each other and light emitting devices arranged around the rectangle array, and also, excepting the side against the skin, all other sides of the photoelectric devices are shielded with light-blocking material.

27. A device as defined in claim 26 wherein there are at least two photoelectric devices arranged both parallel to and vertical to the radial artery respectively, and each device outputs a channel of pulse signal of the radial artery.

28. A device as defined in claim 26 wherein said arterial pulse transducer array should be preferably placed on the inside of the wall of said pressure bladder which closes to the wrist, and the light emitting surface of the light emitting devices and the light receiving surface of the photoelectric devices should face the inner surface of said bladder wall, and the center of the photoelectric device array should correspond to the center of said bladder wall.

29. A device as defined in claim 28 wherein the membrane of said bladder wall close to the wrist, at least its region with arterial pulse transducer array, should be translucent.

30. A device as defined in claim 24 wherein said bladder holding device is preferably a ring-shaped strap made of material with higher rigidity and a little elasticity, the diameter of which is close to that of the wrist, and two ends of the opening of said strap at the back side of the wrist should be connected by non-extensible mean.

31. A device as defined in claim 30 wherein the width of said ring-shaped strap is preferably larger than the diameter of the wrist, and the side of said ring-shaped strap in contact with the wrist should have the contours that match the shape of the wrist.

32. A device as defined in claim 30 wherein said pressure bladder and said ring-shaped strap can be integrated into a whole, which is made by using a strap with certain thickness, and being processed a flat, circular delve whose diameter is the same as that of said pressure bladder on the wrist side of said strap in a position corresponding to radial artery, and the edge of the said bladder wall made with resilient membrane is glued to the edge of circular delve of said strap.

33. A device as defined in claim 24 wherein the wrist holding bracket is required preferably, said wrist holding bracket is a curved board made of material with high rigidity, its length and width should cover the dorsal side of the hand, the dorsal side of the wrist, and the dorsal side of forearm close to the elbow, its shape should make the dorsal side of the hand to form an angle of $100 - 170$ degrees against the dorsal side of the wrist, and cause the palm side of the wrist to form an inward turning angle of $30 - 100$ degrees against the palm side of the part close to the elbow, and preferably also cause the centerline of the hand to form a turning angle toward the little finger against the centerline of the palm side of the wrist.

34. A device as defined in claim 33 wherein the thickness of said wrist holding bracket in the part con-

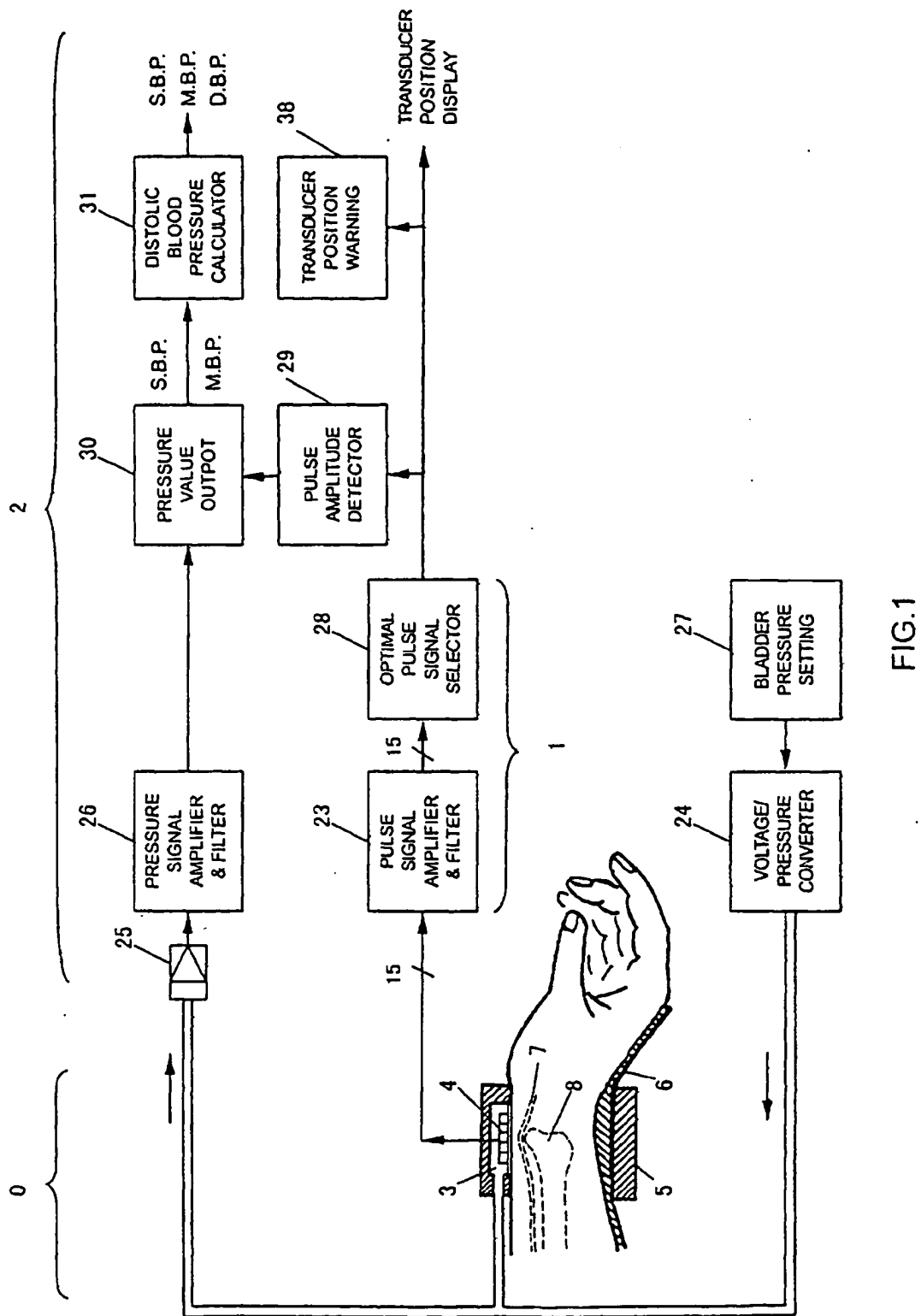
- necting the dorsal side of the hand and the dorsal side of the wrist is increased, so as to eliminate the difference between the diameters of the wrist joint section and that of middle part of the forearm, and to fill the sinking surface of the dorsal side of wrist joint part due to the hand bending to a regular column surface.
35. A device as defined in claim 33 wherein the inside of said wrist holding bracket should be shaped to matches well with the scraggly contour of the dorsal side of the wrist.
36. A device as defined in claim 33 wherein there are fastening devices for holding the arm and the hand on said wrist holding bracket.
37. A device as defined in claim 24 wherein said pressure bladder and arterial pulse transducer can be placed on both the radial artery and the ulnar artery respectively, a switching device is used to control the two pressure bladders and the two arterial pulse transducers to alternately apply the external pressure to both the radial artery and the ulnar artery, and detect volume pulsation signals from both the radial artery and the ulnar artery.
38. A device as defined in claim 37 wherein said ulnar arterial pulse transducer, arranged vertical to the ulnar artery, is preferably made of more than two photoelectric devices placed close to each other, and such photoelectric devices are parallel-connected so as to outputs one channel of pulse signal of the ulnar artery.
39. A device as defined in claim 24 wherein the pressure transducer to be connected to said pressure bladder are integrated with said bladder holding device into a whole.
40. A pulse signal processing device, using any wrist detecting assembly defined in Claim 24 through Claim 39 for non-invasive blood pressure measurement, wherein comprising at least one said wrist detecting assembly which includes at least one said arterial pulse transducer array, the multiple pulse signals output from said arterial pulse transducer array are connected to a optimal pulse signal selector after amplified and filtered.
41. A device as defined in claim 40 wherein said optimal pulse selector choose the optimal pulse signal comprising the steps of, first, choosing a column of the pulse signal with the largest amplitude during the maximum oscillation among all the columns of the pulse signals detected from the transducers arranged parallel to the radial artery in the array; secondly, choosing a channel of the pulse signal from the selected columns of the pulse signals, said selected signal possessing not only maximum oscillation through the entire pressure changing process of the pressure bladder, but also being closed to disappearance during the bladder pressure is higher than the pressure corresponding to the maximum oscillation, and the bladder pressures corresponding to the maximum and the disappearance of oscillation of the selected signal being the lowest; finally, said selected signal being used as the optimal pulse signal.
42. A device as defined in claim 40 or claim 41 wherein, after the optimal pulse signal is selected, a optimal pulse transducer position displaying device is controlled to indicate the exact position of the transducer that detected optimal pulse signal in said arterial pulse transducer array.
43. A device as defined in claim 40 or claim 41 wherein comprising a optimal pulse transducer position warning device to issue warning signals when the transducer that detected the optimal pulse signal shifts away from the center of said arterial pulse transducer array.
44. A device as defined in claim 40 wherein said optimal pulse selector, optimal pulse transducer position displaying device, optimal pulse transducer position warning device are integrated with said wrist detecting assembly into a whole.
45. A non-invasive blood pressure measurement device, using any pulse signal processing device defined in Claim 40 through Claim 44, wherein comprising at least one said pressure bladder and one said wrist detecting assembly which includes at least one said pressure bladder and one said arterial pulse transducer array, the multiple pulse signals output from said arterial pulse transducer array are connected to a optimal pulse signal selector to select one channel of optimal pulse signal, said pressure bladder is connected to both the output of voltage/pressure converter and the input of a pressure transducer of a pressure feeding-measuring system, said optimal pulse signal output from said optimal pulse signal selector is connected to the input of a pulse amplitude testing device of said pressure feeding-measuring system.
46. A device as defined in claim 45 wherein said pressure feeding-measuring system can be used to measure intermittent mean blood pressure, systolic blood pressure, and diastolic blood pressure of the radial artery based on volume oscillometric method.
47. A device as defined in claim 45 wherein said pressure feeding-measuring system can be used to

measure continuous blood pressure wave of the radial artery based on volume compensation method.

48. A device as defined in claim 45 wherein said pressure feeding-measuring system can be controlled by a switching device to alternately measure intermittent mean blood pressure, systolic blood pressure, diastolic blood pressure and continuous blood pressure wave of the radial artery respectively based on volume oscillometric method and olume compensation method.
49. Any device as defined in claim 45 through Claim 48 wherein comprising two independent arterial pulse transducers, two independent pressure bladders and two independent pressure feeding-measuring system, all of which can be alternately used by a switching device to either continuously or intermittently measure blood pressure from the radial artery and the ulnar artery.
50. A device as defined in claim 49 wherein said ulnar arterial pulse transducer is made of several parallel-connected photoelectric devices, after amplified and filtered, the ulnar arterial pulse output from said arterial pulse transducer is connected to the input of the pulse amplitude testing device of said pressure feeding-measuring system used for measuring blood pressure of the ulnar artery.
51. A device as defined in claim 49 wherein sharing the common parts of two independent pressure feeding-measuring system used respectively to measure blood pressure from the radial artery and the ulnar artery, said common parts are those except for said signal amplifier, filter, optimal pulse signal selector, and pulse amplitude testing device.
52. Any device as defined in claim 49 through Claim 51 wherein sharing one pressure feeding-measuring system for measuring blood pressure from the radial artery and the ulnar artery, and when measuring blood pressure from one of the two arteries, said pressure feeding-measuring system is controlled by a switching device to alternately connect to the tubing of said pressure bladder and the output of said arterial pulse transducer placed on the artery being measured.
53. A device as defined in claim 49 or claim 50 wherein comprising a calibrating device that uses the results of blood pressure measured from the radial artery to calibrate the results measured from the ulnar artery.
54. A device as defined in claim 49 wherein said optimal pulse selector, optimal pulse transducer position displaying device, optimal pulse transducer po-

sition warning device, as well as pressure feeding-measuring system can be integrated with said wrist detecting assembly into a whole.

55. A device as defined in claim 49 or claim 54 wherein said non-invasive blood pressure measuring device can be integrated with a blood pressure recording device into a whole.
56. A device as defined in claim 49 or claim 54 or claim 55 wherein said non-invasive blood pressure measuring device can be integrated with the monitor for measuring and recording other physiological signals into a whole.
57. Any device as defined in Claim 49 or Claim 54 through Claim 56 wherein said non-invasive blood pressure measuring device can be connect to some communication devices.



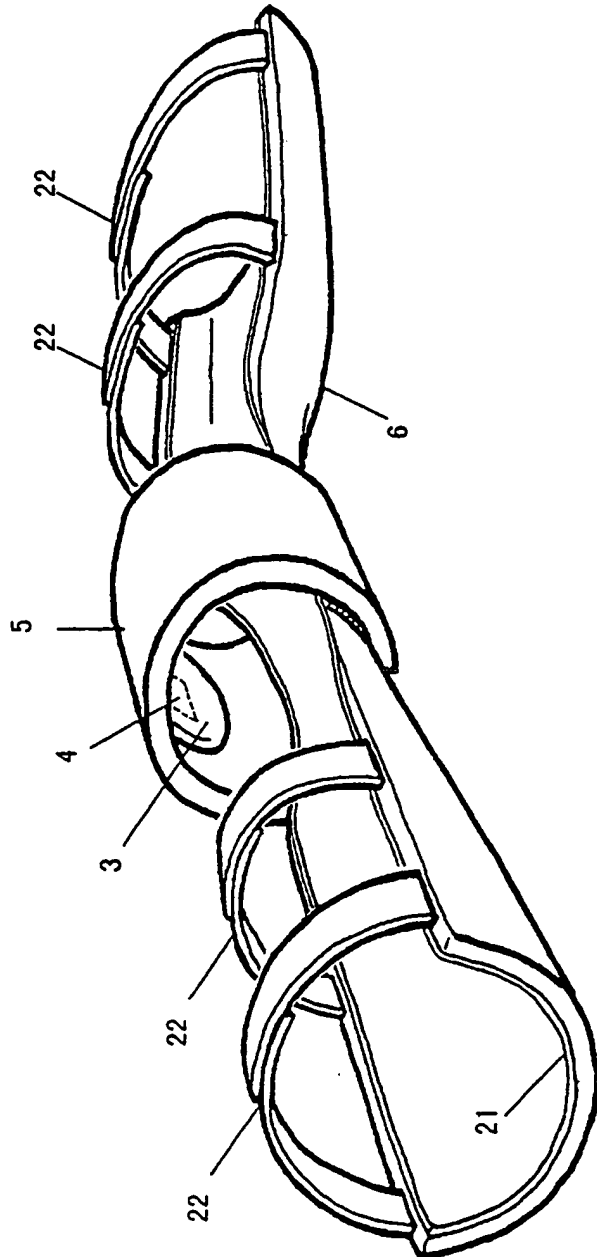


FIG.2

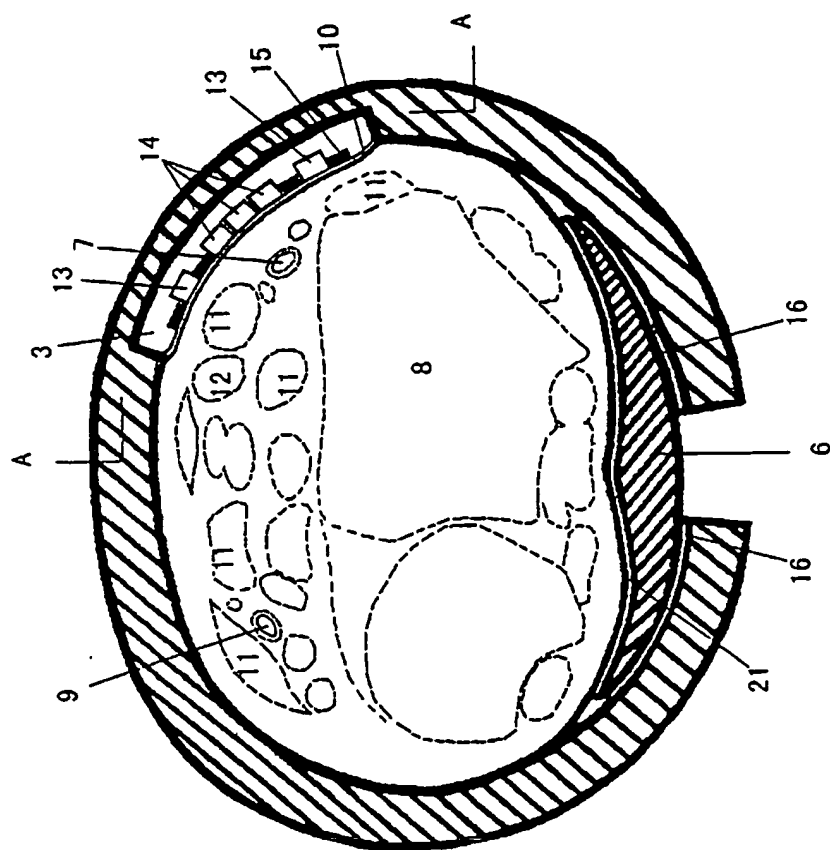


FIG.3

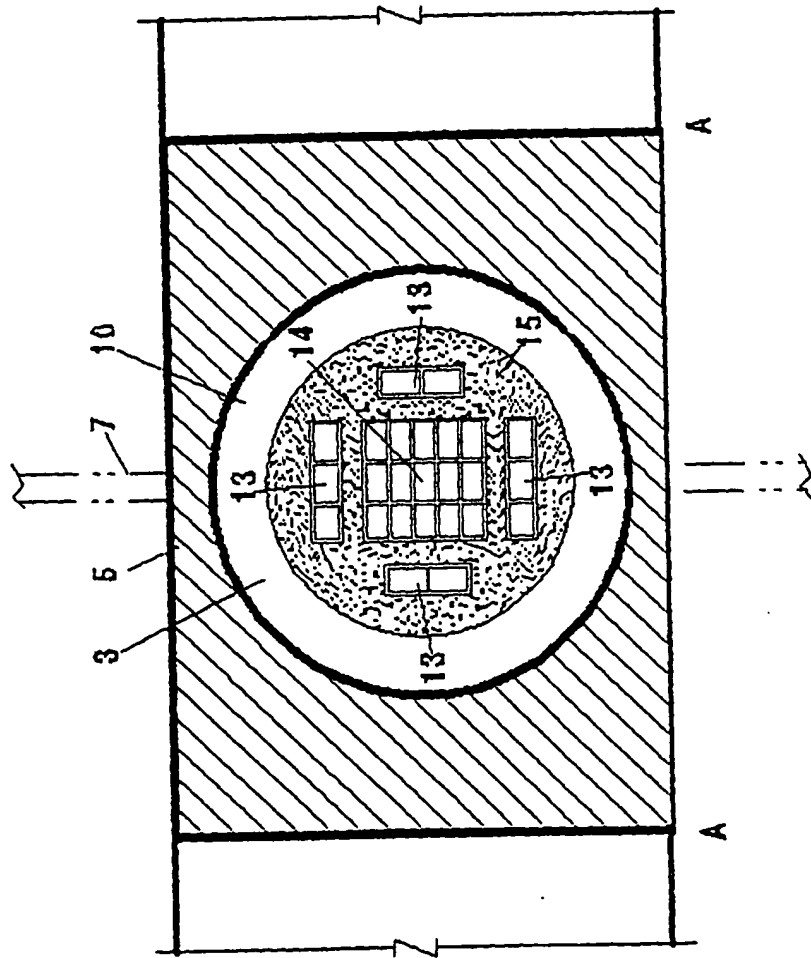


FIG.4

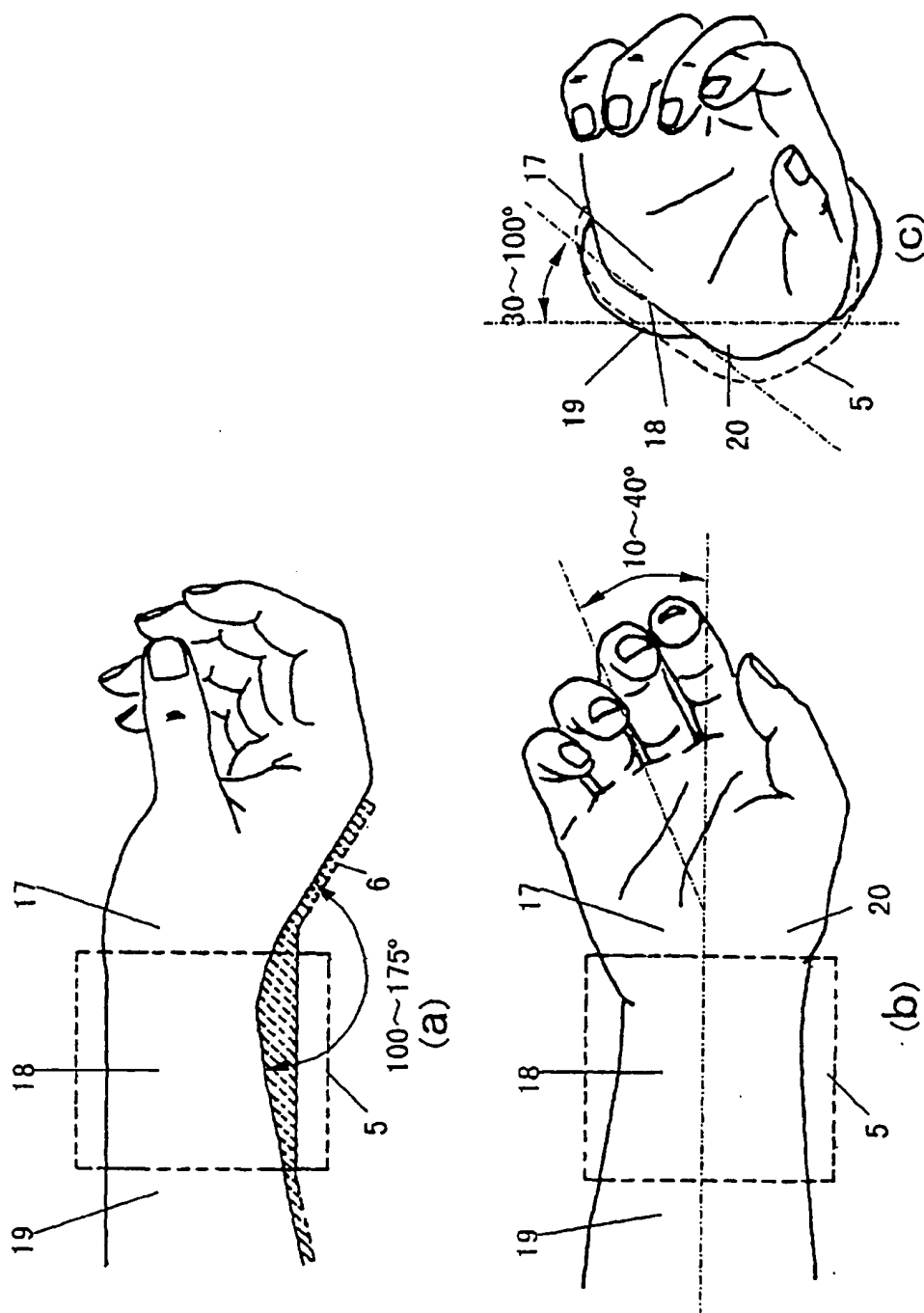


FIG.5

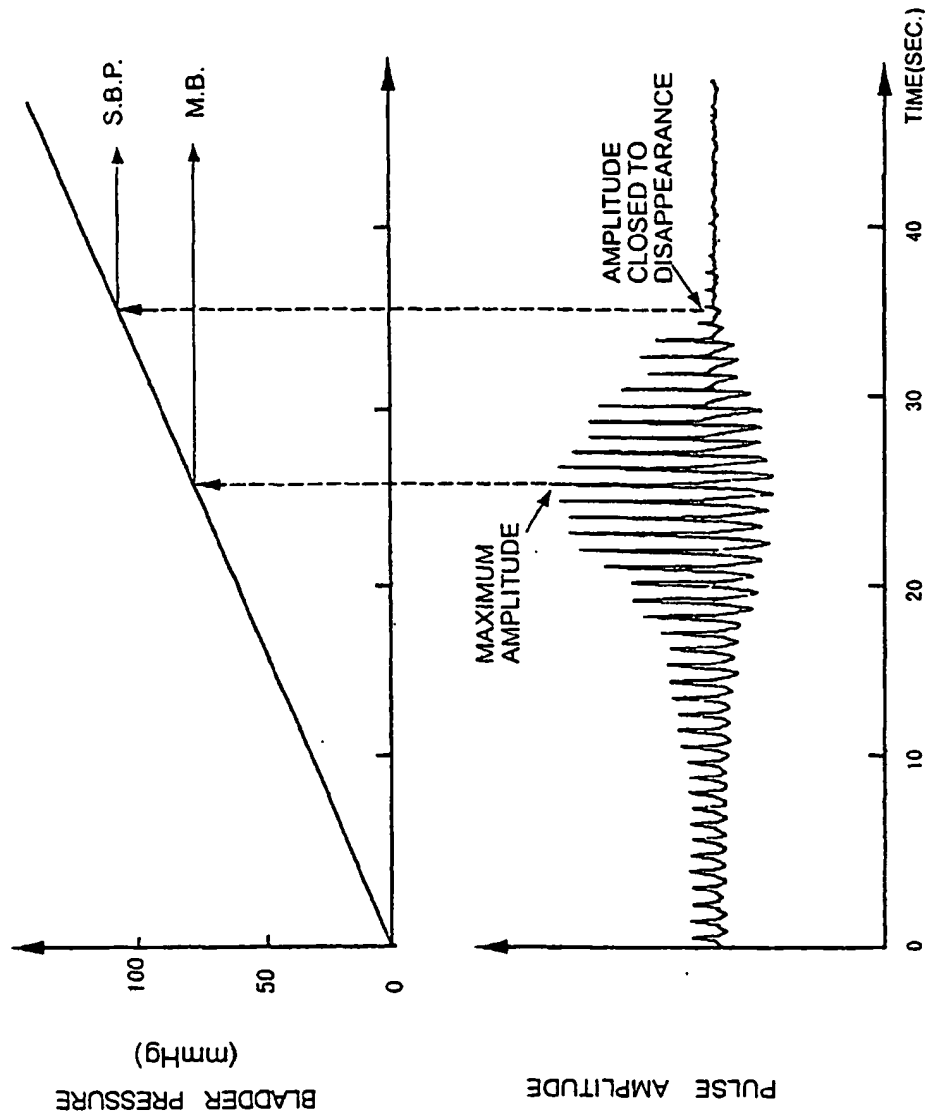


FIG.6

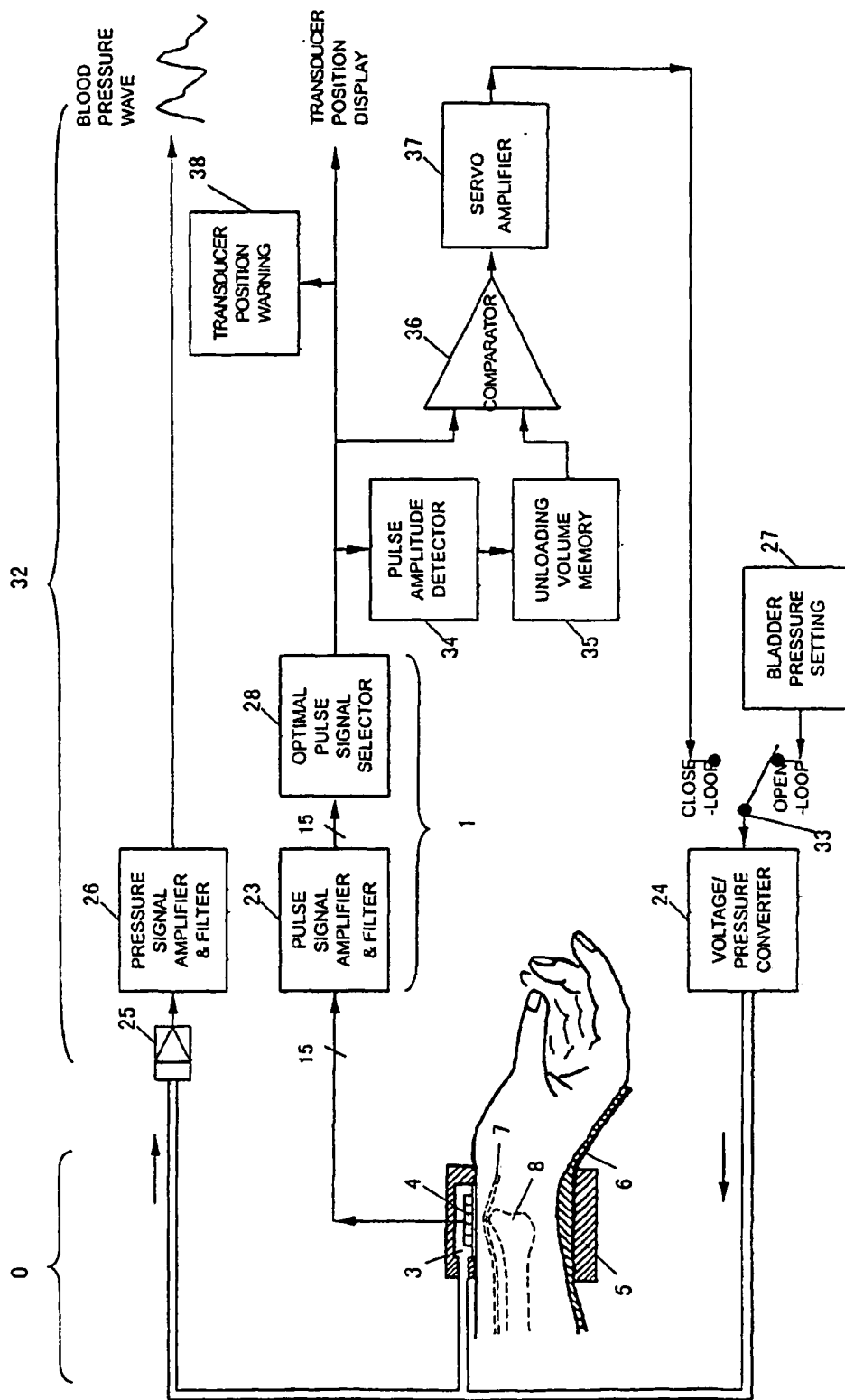


FIG.7

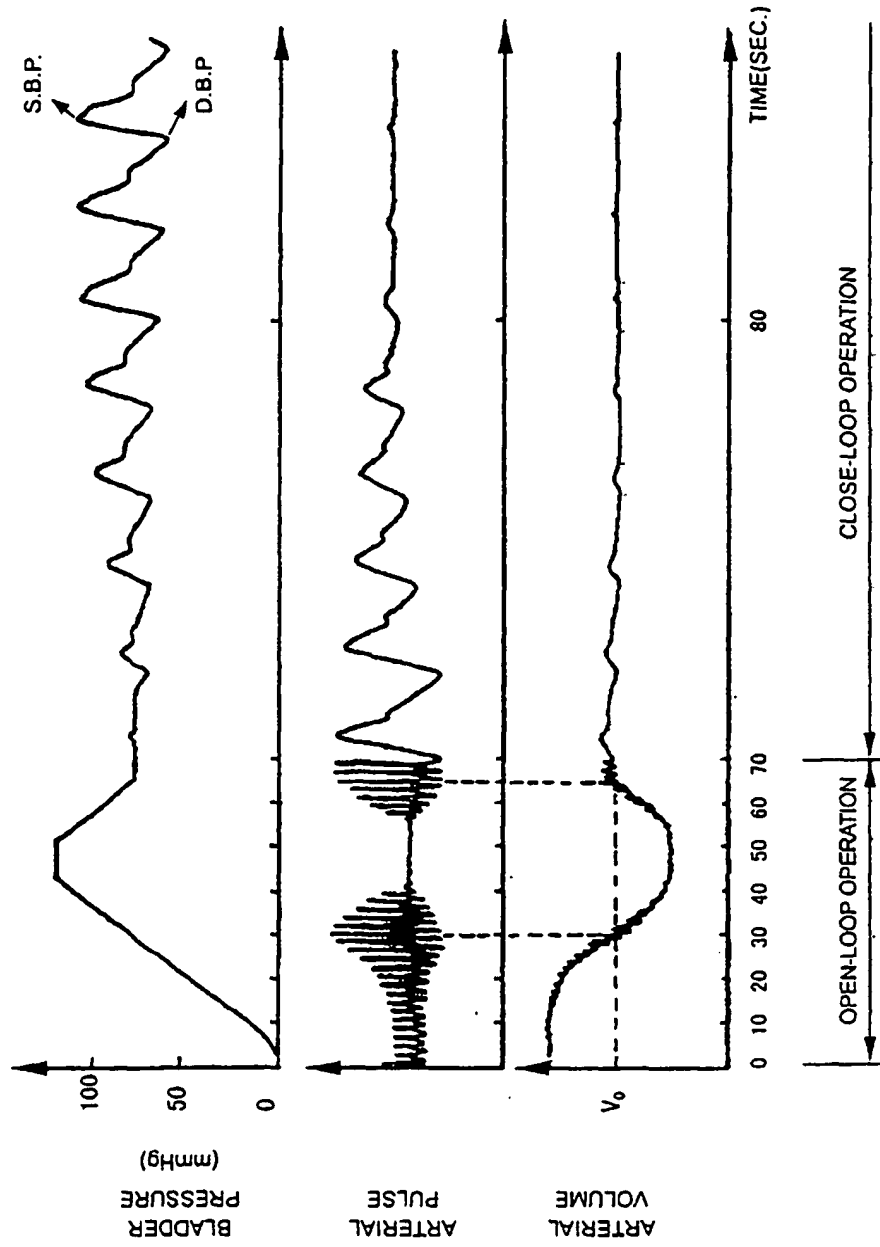


FIG.8

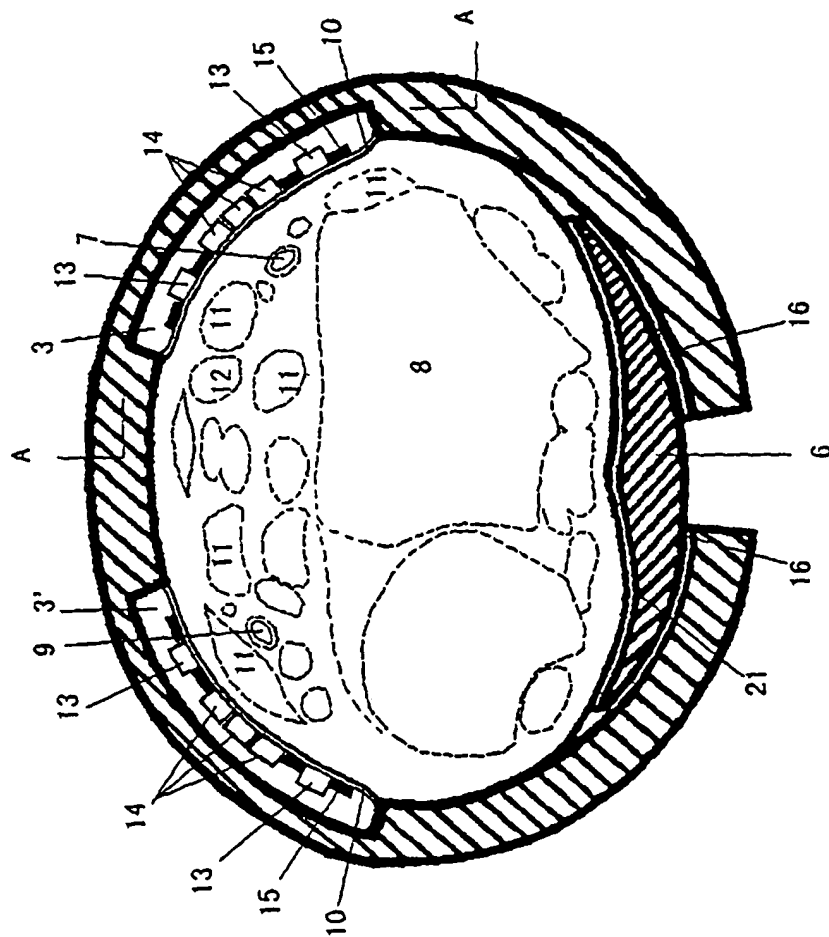


FIG.9

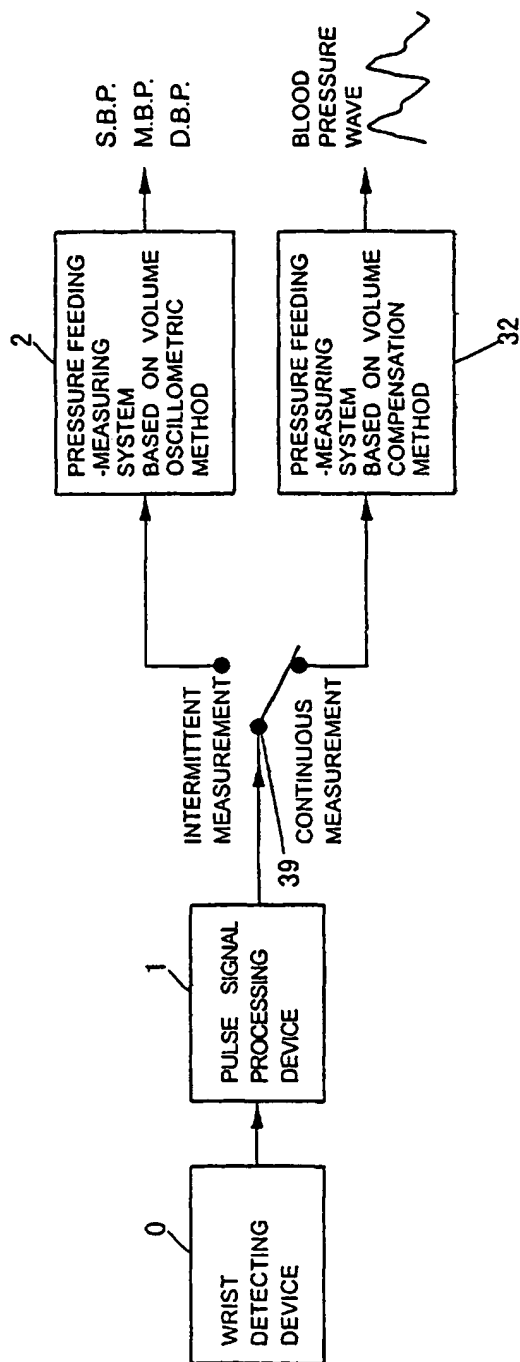


FIG.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN00/00097

A. CLASSIFICATION OF SUBJECT MATTER

IPC² A61B5/021

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC² A61B5/021, 5/022, 5/0225, 5/023, 5/02, 5/00, A61M5/32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Chinese Patent

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CNPAT EPODOC WPI PAJ; KEYWORDS: blood pressure, measure, noninvasive, positioning, wrist
Pulse wave, sensor, transducer, bladder, bellow

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P. X	CN2371945Y (Lu, Weiming) 05 Apr 2000 (05.04.00) page 7, line 11-18, figure 1-2	1-4
X	US4993422A (The Hon Group) 19 Feb 1991 (19.02.91) column 7, line 15-32, figure 2, 10	1-4
X	US4369774A (Frederick F. Auerbach) 25 Jan 1983 (25.01.83) column 2, line 36-60, figure 1-3	1-2

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim (S) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
28 Aug 2000 (28.08.00)

Date of mailing of the international search report

14 SEP 2000 (14.09.00)

Name and mailing address of the ISA/CN
6 Xitucheng Rd., Jimen Bridge, Haidian District,
100088 Beijing, China
Facsimile No. 86-10-62019451

Authorized officer

ZHANG XIAO

Telephone No. 86-10-62093956



Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN 00/00097

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US4799491A(SRI International) 24 Jan 1989 (24. 01. 89) entire document	5-9, 12-15, 23, 24, 25 30, 40-43
X	US5033471A (Colin Electronics Co., Ltd) 23 Jul 1991 (23. 07. 91) entire document	5, 6, 9, 12-15, 23, 24, 40, 41
X	US4987900A(Colin Electronics Co., Ltd) 29 Jan 1991 (29. 01. 91) entire document	24, 25, 30, 40-43
X	WO9712542 A1(HON. Edward, H) 10 Apr 1997 (10. 04. 97) entire document	24
X	US5170796A(Colin Electronics Co., Ltd) 15 Dec 1992 (15. 12. 92) entire document	5-7, 9, 12-14, 24, 25, 40, 42
X	US5497779A(Colin Corporation) 12 Mar 1996 (12. 03. 96) entire document	5-7, 9, 12-14, 24, 25, 40, 42
X	US5772601A (Colin Corporation) 30 Jun 1998 (30. 06. 98) entire document	5, 6, 9, 24, 40

Form PCT/ISA/210 (continuation of second sheet (1)) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN00/00097

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos: 45-57
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

- A positioning method of noninvasive blood pressure measurement (claim 1)
- A method of noninvasive blood pressure measurement (claim 5)
- A wrist detecting apparatus of noninvasive blood pressure measurement (claim 24)
- A pulse signal processing apparatus of noninvasive blood pressure measurement (claim 40)

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)